



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,682	08/15/2002	Peter Joseph Ayre	DUMMER13.001APC	6855

20995 7590 03/04/2004

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER

LAYNO, CARL HERNANDZ

ART UNIT	PAPER NUMBER
----------	--------------

3762

DATE MAILED: 03/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/980,682

Applicant(s)

AYRE ET AL.

Examiner

Carl H. Layno
3/2/04

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46, 48-58, 60-62 and 64-96 is/are pending in the application.
- 4a) Of the above claim(s) 70-72 and 93-96 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 86-92 is/are allowed.
- 6) ☒ Claim(s) 1-28, 73, 74, 77-79 and 81 is/are rejected.
- 7) ☒ Claim(s) 29-46, 48-58, 60-62, 64-69, 75, 76, 80 and 82-84 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 August 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/2</u> | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 3762

DETAILED ACTION

Election/Restrictions

1. Claims 70-72 and 93-96 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Groups II and III, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 10.
2. Claims 1-69 and 73-92 are active.

Information Disclosure Statement

3. Acknowledgment is made of applicant's Information Disclosure Statements (PTO-1449) which were received by the Office on February 20, 2002 and on August 15, 2002. These documents have been made of record in the file as Paper Nos.3 and 7, respectively.

Drawings

4. The drawings are objected to because of the following minor informalities:

-In all Drawing Sheets, the captions "SUBSTITUTE SHEET (RULE 26)" and "PCT/AU00/00355" should be deleted.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

5. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

In applicant's submitted application, **claims 47, 59, 63, and 85 are missing.**

Therefore, misnumbered claims 48-96 been renumbered as claims 47-92.

6. Claims 82-84 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Specifically, **claims 82-84 depend from a non-existent claim 63.** To overcome this objection, the Examiner suggests changing the dependency of these claims to depend from claim 73.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 79 and 81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regard to claim 79, in line 1 a reference is made to the "HQ characteristic". This is indefinite since it is unclear what the acronym "HQ" stands for (i.e. it was not previously

Art Unit: 3762

defined). To overcome this rejection, the Examiner recommends defining this acronym upon its first use.

Claim 81 is also rejected since it depends from rejected claim 79.

Double Patenting

9. Claims 1-8, 11-16, 18-22, and 25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 19-27, 8-11, and 13-18, respectively, of U.S. Patent No. 6,250,880. Although the conflicting claims are not identical, they are not patentably distinct from each other because they describe the same blood pump features.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States.

11. Claims 1-27 are rejected under 35 U.S.C. 102(d) as being barred by applicant's published PCT application WO 99/12587 (cited by the Applicant as prior art).

The applicant's '587 published PCT application, cited as prior art, describes a rotary pump 1 with a hydrodynamically suspended impeller 100 (Fig.1) within a pump housing 2. The

Art Unit: 3762

pump housing comprises a "first face" front part 3 and a "second face" back part 4, each having a deformed surface to fit the contour of the impeller 100. A number of localized normal forces caused by the impeller are countered by resistive/"restoring" forces from thrust bearings (p.4, lines 10-21) to keep the impeller 100 suspended.

In regard to claim 12, see Fig.3B.

12. Claims 28, 73, 74, 77, and 78 are rejected under 35 U.S.C. 102(b) as being anticipated by Hubbard et al '525.

The Hubbard et al '525 patent, cited by the applicant as prior art, describes a blood flow measurement system (Fig.1) including a blood pump 16 enclosing an impeller 24 having a fluid inlet 14 and a fluid outlet 12. The impeller is driven by motor 28 having a shaft and coupling 30. A motor control 34 and console control computer 36 utilize inputs from a speed sensor (RPM) 38 and current sensor (not numbered -- Fig.2) to obtain torque/power measurements and an estimate of flow rate (Fig.2). Note that the motor control 34 maintains the speed of the impeller at or near a predetermined speed by setting an "RPM SET" signal through inputs 40, which may be thumbwheel switches or a keyboard (col.2, lines 45-51).

Allowable Subject Matter

13. Claims 29-46, 48-58, 60-62, 64-69, 75, 76, 80, and 82-84 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Art Unit: 3762

14. Claims 86-92 are allowed.

15. As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

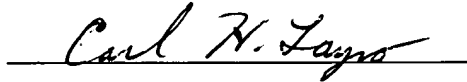
The Khanwilkar et al '180 and '661 patents are cited for their pertinent use of a implantable blood pump whose impeller is suspended between two deformed surfaces. Unlike applicant's device, however, those of Khanwilkar et al rely upon magnetically suspending their impellers rather than exclusively using hydrodynamic suspension.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (703) 308-3694. The examiner can normally be reached on Monday thru Thursday from 9 AM to 6 PM and every other Friday between 9AM and 5PM. A voice mail or E-mail message (carl.layno@uspto.gov) may be left if desired.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes, can be reached on (703) 308-5181. All faxed correspondence should be sent to the Office's new Official FAX number (703) 872-9306.

Art Unit: 3762

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Legal Instruments Examiner (LIE) Brenda Webb whose telephone number is (703) 305-7520.

A handwritten signature in cursive script, reading "Carl N. Layno", is written over a horizontal line.

CARL LAYNO
PRIMARY EXAMINER

CHL
3/2/04